

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B	A2	(11) International Publication Number: WO 00/44274 (43) International Publication Date: 3 August 2000 (03.08.00)
(21) International Application Number: PCT/US00/02418 (22) International Filing Date: 28 January 2000 (28.01.00) (30) Priority Data: 60/117,966 29 January 1999 (29.01.99) US (71)(72) Applicants and Inventors: POUGATCHEV, Vadim I. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). BOGOMOLOV, Evgueni N. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). IAROSLAVSTEV, Igor V. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). ZHIRNOV, Eugene N. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). GRIBKOV, Eugene N. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). (74) Agent: JOHNSON, Larry, D.; Suite 130, 175 N. Redwood Drive, San Rafael, CA 94903 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: PERSONAL PHYSIOLOGICAL MONITOR (57) Abstract A personal physiological monitor for evaluating autonomic nervous system functioning, said monitor including PPG, and/or GSR, and/or temperature sensors for acquiring raw physiological signals; a data processor for computing interbeat intervals from the raw PPG signal and re-sampling interbeat interval sequences with a linear interpolation procedure; transmission means for transmitting both raw signals and the interbeat intervals to a computer through a communication port; a visual display; and built-in flash memory.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

PERSONAL PHYSIOLOGICAL MONITOR

DESCRIPTIONTECHNICAL FIELD

5 This invention is related to the subject of the
monitoring and assessment of the specific physiological
conditions reflecting the functions of the autonomic
nervous system (ANS) - heart rate variability, blood
volume pulse, galvanic skin reactions (GSR) and peripheral
10 skin temperature (TMP).

BACKGROUND ART

 It is known that the overall functioning of a living
organism is controlled by the autonomic nervous system.
15 The ANS has two antagonistic branches - the sympathetic
and parasympathetic nervous systems. Every organ is
activated by one branch and inhibited by the other.
Generally when the organism is in a calm state
(relaxation, sleep, etc.) several organs, including the
20 heart, lungs and blood vessels, are under the dominance of
parasympathetic control. When the organism is activated by
physical activity, psycho-emotional arousal or stress, the
organs are under dominant control of the sympathetic
nervous system. A healthy organism is capable of adjusting
25 to any outer influence by means of a quick and adequate
sympathetic response. Once that factor disappears the
parasympathetic activity increases balancing the
organism's overall autonomic regulation.

 It is important to have a means of measuring these
30 specific physiological parameters used for the evaluation
of the level of balance between the branches of autonomic
nervous system and their reactions. With such means,
specific provocative test factors are evaluated as well as
the condition of both branches. Such a tool can help a
35 human being learn how to cope with stress, thereby
achieving an autonomic balance as well as measuring
certain physiological effects of the autonomic nervous
systems regulations.

One of the most informative methods for the evaluation of the status of ANS sympathetic and parasympathetic branches is heart rate variability analysis. It is known that the time intervals between each two consecutive heartbeats vary and are under control of the autonomic nervous system. When the parasympathetic system is dominant the heart interbeat intervals (IBI) are oscillating with higher frequencies (0.15 - 0.4 Hz). When sympathetic arousal occurs, lower frequency oscillations take place.

There are two other physiological modalities that reflect the condition of autonomic regulation: skin conductance (galvanic skin response: GSR) and peripheral skin temperature. Skin conductance reflects changes in sweat gland activity driven by involuntary arousal of the sympathetic nervous system. These changes are rapid and varied as a reaction of the organism to outer events and slower changes reflecting variations of overall tonus of the sympathetic system. The skin temperature reflects a degree of vasoconstriction or dilation of the peripheral blood vessels, which also reflects a long-term process of the interaction of both branches of autonomic nervous systems. There is some disagreement regarding the efficacy of these latter two modalities for evaluating ANS balance, so they are noted here for reference purposes only.

Another physiological measure - blood volume pulse reflects the level of peripheral blood vessels constriction / dilation. Blood volume pulse is affected by the same autonomic function activity.

There is a standard mathematical procedure for short-term HRV evaluation, suggested by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology (1996). It provides both time and frequency domain analysis of the IBI time series. There are three important parameters of frequency domain analysis of HRV that reflect the levels of sympathetic and parasympathetic activities and their balance. The high frequency range (0.15 Hz- 0.4 Hz) of the

IBI power spectrum (HF) reflects parasympathetic influence on heart rate. The low frequency range (0.04 Hz - 0.15 Hz) of the IBI power spectrum (LF) has a considerable input of the both branches of the autonomic nervous system.

5 To perform the HRV analysis an electrocardiograph (ECG) signal is usually measured. The IBI are derived from the ECG as the intervals between consecutive R-peaks. This method is very accurate and reliable but has a serious disadvantage - it requires the use of complex ECG
10 equipment with the inconvenience of multiple site electrode placement. An alternative is to use a photoplethysmograph (PPG) measurement, which is a portable and convenient optical sensor that can be applied in many places to pick up peripheral blood flow changes (e.g.
15 fingers, ear lobe, etc.). The PPG emits an infrared (IR) light on the skin. The emitted light is partially consumed by the blood flow. The degree of light consumption / reflection is proportional to the changes in blood flow. The PPG signal has periodic peaks that represent flow
20 pulsation in blood vessels. It can be used to derive the IBI by measuring the time between two PPG peaks. Blood volume pulse information can be derived as well.

DISCLOSURE OF INVENTION

25 The personal physiological monitoring method of the present invention includes several possible hardware configurations of the physiological monitoring apparatus. Generally a physiological monitor continuously carries out any of the following functions depending on the particular
30 hardware configuration:

1. Acquires raw signals any of the following physiological modalities: PPG, GSR or temperature;
2. Computes interbeat intervals from the raw PPG signal;
- 35 3. Re-samples interbeat interval sequence with a linear interpolation procedure;
4. Transmits both raw signals and the interbeat intervals to a computer through a communication port;

5. Displays data on an LCD display in the case of a standalone device configuration; and

6. Stores data in built-in flash memory with the possibility to download data to a computer.

5 The present invention may be embodied in either a standalone physiological monitoring device or in a computer-based unit.

BRIEF DESCRIPTION OF THE DRAWINGS

10 Figs. 1a depicts the standalone unit embodiment of the personal monitoring apparatus of the present invention;

Fig. 1b shows the LCD module and wireless IR or RF module of the standalone embodiment transmitting a signal to a remote computer;

Fig. 2a shows a finger sensor unit as held by a user;

Fig. 2b shows detail of the finger sensor pad that may be secured to the finger of a user;

Fig. 3a illustrates the use of a physiological monitoring system having sensors integrated into a typical computer mouse;

Fig. 3b shows details of the mouse of the embodiment of Fig. 3a;

Fig. 4 is a schematic block diagram showing the structural and functional elements of the invention;

Fig. 5 is a schematic block diagram of the 3-channel physiological monitor;

Fig. 6 illustrates how PPG sensor electronic circuitry of the present invention operates; and

Fig. 7 illustrates the procedure of IBI computation carried out by the micro-controller.

BEST MODE FOR CARRYING OUT THE INVENTION

35 Figs. 1a and 1b depict a first preferred embodiment 10 of the personal physiological monitoring apparatus of the present invention, particularly illustrating the standalone unit concept. It can be implemented in the form of a glove combined with a flexible wristband. The soft

glove 11 supports embedded sensors in any combination of PPG 12, GSR 14 and temperature 16, all of which are well known in the art. Collectively, these elements comprise the sensor unit. The sensors are wired to a main processing unit 18 embedded in a flexible wristband 20, which also supports an LCD module 22. The main processing unit includes a battery unit 24, which powers the main processing unit and which is also connected to the sensors via sensor circuits 17 to provide power to the sensors sufficient to conduct their respective measurements. It may also include a flash memory module 28 to collect physiological data and a wireless infrared (IR) or radio frequency (RF) module 30 capable of transmitting a signal 32 for downloading of the data to a remote computer 34.

When the above-described glove is worn by a user, all built-in sensors come in contact with the user's skin. When the device is turned on, it begins to continuously scan all available sensors and display the resulting data on an LCD display module. If there is a flash memory module installed, this data is collected in a compact format providing up to 24-hour data storage. At any time the user may command that all collected data be wirelessly downloaded to the remote computer. In fact, this design could allow for a continuous real-time data transmission to the remote computer instead of saving in a flash memory with respective download.

Figs. 2a, 2b, 3a, and 3b depict a computer-based unit concept. There are two different implementations of the device: Fig. 2a shows a finger sensor unit 40 in use; Fig. 2b shows detail of the finger sensor pad 42 that may be placed on a finger and secured, for example, with a strip of hook and loop fastening material (not shown).

In a finger sensor pad design, Fig. 2a, there are up to three sensors located on top of the pad: PPG optical sensor window 44, two GSR electrodes 46 and a temperature sensor 48. All physiological signals are sent to the data processing unit 50 that processes the signals and transmits digital information to the computer 52 via

serial interface 54.

Fig. 3a illustrates the use of a mouse-based physiological monitoring system 60 having sensors integrated into a typical computer mouse; and Fig. 3b shows details of the mouse of this embodiment. In a mouse-integrated sensor design concept, Figs. 3a and 3b, there are up to three sensors integrated into the body of the computer mouse. To provide better contact between sensors and the skin, a PPG sensor 62 and/or a temperature sensor 64 can be placed on the lateral side of the mouse 66 where a thumb is normally situated when mouse is in a grip. Two GSR electrodes (metal plates or conductive rubber patches) 68 can be placed either on the left and right mouse buttons where two fingers are typically situated or can be placed on the top of the mouse body to maintain contact with the palm surface when mouse is in a grip. All physiological signals are sent to the data processing unit 70 that processes the signals and transmits digital information to the computer 72 via the serial interface 74.

Fig. 4 is a schematic block diagram showing the structural and functional elements of the invention. The device measures any combination of the physiological signals of PPG 80, GSR 82 and temperature 84 by means of the respective sensors that are combined in one device. The device has a built-in microprocessor 86 that controls all of the functions and processing of the PPG signal to derive the IBIs. In the case of the computer-based design (finger pad or mouse-integrated device) all physiological data is transmitted to the computer via serial interface (RS232 port, USB port, wireless infrared (IR) or radio (RF) port) 88. In case of standalone design physiological data is displayed on built-in LCD display 90 and can be stored in the flash memory module 92. Data collected in the flash memory 92 can be downloaded to the computer via the serial port 88. Depending on the particular design concept the device can be powered from the power supply 94 built into device (standalone or wireless models) or from

the computer via USB port. It can also be powered via RS232 port if the model does not include the GSR sensor. The specific software could collect physiological data via the specific device driver 96 to perform certain tasks like physiological monitoring, evaluation or training.

Fig. 5 is a schematic block diagram of the 3-channel physiological monitor 100. This particular design describes a mouse-integrated version of the monitor as an example. A standalone device is equivalent to this embodiment, excluding the mouse-specific components of X-coordinate control circuitry, Y-coordinate control circuitry, and push buttons control circuitry. The photo sensor 102 consists of two 880nm IR emitters 104 and one 880nm IR detector 106. Such a combination provides better movement artifact reduction. The micro-controller 108 carries out all the signal process functions of the device. An input signal goes to the internal sample and hold circuit 110 of the micro-controller passing an input amplifier 112 and an analog one-pole high-pass filter 114. This allows for input signal conditioning. The sample and hold circuit 110 is connected to the cascade of an output amplifier with built-in band-pass filter 116 and a one-pole low-pass filter 118. The output of this cascade is connected to the input multiplexer of the 12-bit analog-to-digital converter 120. The signals from GSR electrodes and temperature sensor (thermoresistor) go to the input multiplexer of A-to-D converter 120 passing a low-pass filter 122. The current source 124 provides both GSR and TMP sensor circuits with the necessary power to conduct the measurements. The power supply 126 is preferably one of two types: (A) two AAA batteries with switching voltage regulator or (B) one 9-V battery with a linear voltage regulator. However, the apparatus may be modified to run from any of a number of other suitable power sources. The micro-controller 108 carries out sensor functioning, interbeat interval computing as well as standard mouse functioning along with X-coordinate 128, Y-coordinate 130 and push button 132 control circuitry. It also provides a

serial interface communication with a serial port 134 of a computer 136.

Fig. 6 demonstrates how the PPG sensor electronic circuitry operates. The operation of GSR and TMP is not reflected here because of its extreme simplicity. The micro-controller generates square 200uS-long (T_p) impulses 140 with 3.3V amplitude and 2mS periods (T_e) pulse 142, sent to the IR emitter. The use of switch power mode provides better power consumption and eliminates an excessive sensitivity to the external lights. An output signal of the IR detector is a function of the intensity of the signal reflected by the skin surface. The output signal of the IR detector is sent to the input of the analog switch of the micro-controller through the input amplifier (current-to-voltage converter with a gain) and the high-pass filter to eliminate a signal offset 144. The micro-controller controls an internal analog switch in a "Sample and Hold" mode 146, switching the capacitor Ch between an output of the input amplifier and an input of the output amplifier, so Ch holds constant voltage depending on the input signal 148. The output amplifier is an AC amplifier with a built-in band-pass filter and gain of 70 appr. It provides an output signal in the voltage range of the A-to-D converter 150. The micro-controller carries out the PPG signal processing and sends data to the PC.

Fig. 7 illustrates the procedure of IBI computation carried out by the micro-controller. The raw PPG signal 160 varies in the range of 0 ... 1000 units. It is filtered by a low-pass digital filter (2.5 Hz cut-off). The LP filter gives a filtered signal 162 that looks almost like a sine wave. Then the signal is filtered by a high-pass digital filter (0.5 Hz cut-off). The HP filter gives a signal 164 that is oscillating at around zero. Then IBI (interbeat intervals) are computed as the time intervals between the moments when the signal is crossing a zero line. So the IBI sequence 166 gets every new value at the moment of next crossing of the zero line. The

sequence of the interbeat intervals also called periodogram has an irregular nature, in other words, the time intervals between its elements are not constant. This is because of the moments when next PPG peak occurs are not predictable. The micro-controller then does a re-sampling procedure to convert a periodogram into a stabilized sequence of IBI values by means of linear interpolation 168. This allows for the processing of signals to do spectral analysis of IBIs to evaluate the various physiological parameters.

While this invention has been described in connection with preferred embodiments thereof, it is obvious that modifications and changes therein may be made by those skilled in the art to which it pertains without departing from the spirit and scope of the invention. Accordingly, the scope of this invention is to be limited only by the appended claims and equivalents.

PERSONAL PHYSIOLOGICAL MONITOR

CLAIMS

What is claimed as invention is:

1. A personal physiological monitoring apparatus
5 for monitoring autonomic nervous system balance,
comprising:
a sensor unit;
power means;
a plurality of sensors operatively located in said
10 sensor unit so as to be in contact with the skin of the
user when in use, said sensors selected from the group
consisting of photoplethysmograph (PPG) sensors, galvanic
skin response (GSR) sensors, and peripheral skin
temperature (TMP) sensors, said sensors for the
15 acquisition and transmission of raw physiological data;
sensor circuits connecting said sensors to said power
means;
a data processing unit electrically connected to
power means and to said plurality of sensors, said data
20 processing unit receiving the raw physiological data
transmitted by said sensors and including means for
evaluating the raw data for autonomic nervous system
balance and for providing display output; and
display means for displaying the display output from
25 said data processing unit.
2. The apparatus of claim 1 further including
memory means for collecting the raw physiological data for
downloading the data to a remote computer.
3. The apparatus of claim 2 wherein said memory
30 means comprises a flash memory module.
4. The apparatus of claim 1 further including
transmission means for transmitting raw physiological data
to a remote computer having means for evaluating said data
to assess ANS functioning and balance.
- 35 5. The apparatus of claim 4 wherein said
transmission means comprises a wireless infrared module.
6. The apparatus of claim 4 wherein said
transmission means comprises a wireless radio frequency

module.

7. The apparatus of claim 1 wherein said transmission means provides continuous real-time data transmission to a remote computer.

5 8. The apparatus of claim 1 wherein said display means comprises a video display monitor.

9. The apparatus of claim 1 wherein said display means comprises a flexible wristband having an LCD display.

10 10. The apparatus of claim 1 wherein said sensors include at least one PPG sensor for transmission of a raw PPG signal to said data processing unit.

11. The apparatus of claim 10 wherein said data processing unit includes means for computing interbeat intervals from the raw PPG signal and resampling the interbeat interval sequence with a linear interpolation procedure.

12. The apparatus of claim 1 wherein said sensor unit comprises a glove having embedded sensors that bring sensors into contact with the wearer's skin when in use..

13. The apparatus of claim 1 wherein said sensor unit comprises a finger sensor pad and further includes means for securing said finger sensor pad to the finger of a user, and further including a data interface connecting said finger sensor pad to a computer.

14. The apparatus of claim 1 wherein said sensor unit comprises a computer mouse, and further includes a data interface connecting said mouse to a computer.

15. A method of monitoring autonomic nervous system functioning, comprising the steps of:

providing a personal physiological monitoring apparatus for monitoring autonomic nervous system balance, said apparatus comprising a sensor unit, power means, a plurality of sensors operatively located in said sensor unit so as to be in contact with the skin of the user when in use, said sensors selected from the group consisting of photoplethysmograph (PPG) sensors, galvanic skin response (GSR) sensors, and peripheral skin temperature (TMP)

sensors, said sensors for the acquisition and transmission of raw physiological data, sensor circuits connecting said sensors to said power means, a data processing unit electrically connected to power means and to said

5 plurality of sensors, said data processing unit receiving the raw physiological data transmitted by said sensors and including means for evaluating the raw data for autonomic nervous system balance and for providing display output, and display means for displaying the display output from
10 said data processing unit; and

securing said sensor unit to the skin of the subject to be monitored.

16. The method of claim 15 wherein said sensor unit comprises at least one PPG sensor.

15 17. The method of claim 16 wherein said data processing unit includes means for computing interbeat intervals from the raw PPG signal and resampling the interbeat interval sequence with a linear interpolation procedure.

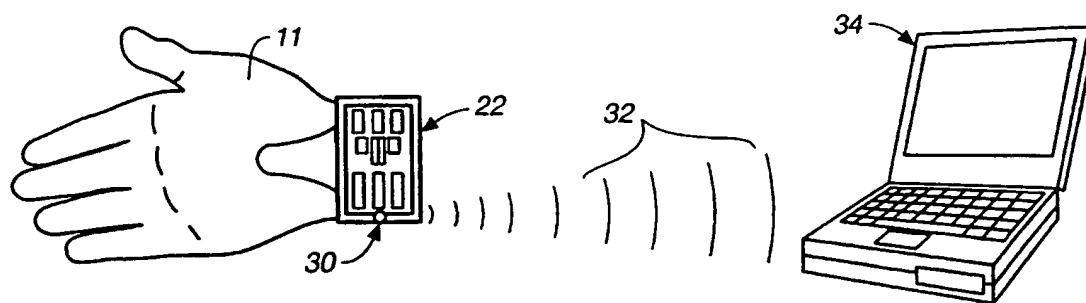
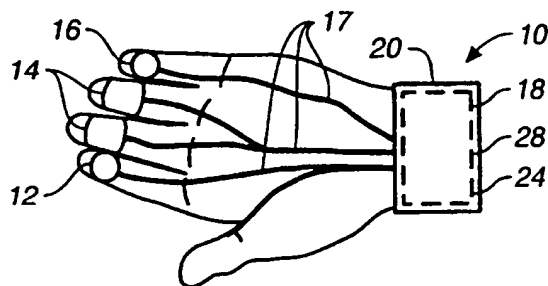
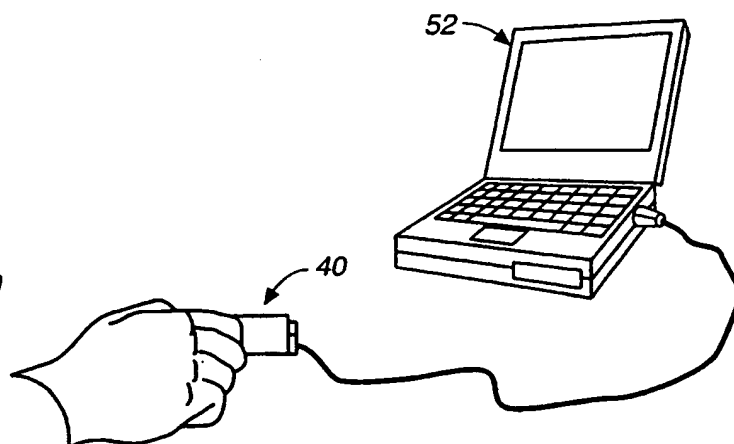
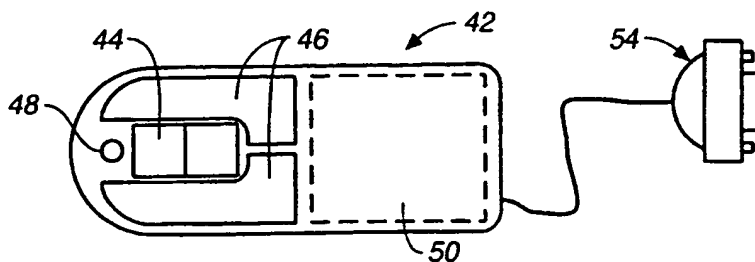
20 18. The method of claim 17 wherein said personal physiological monitor includes transmission means for transmitting both raw signals and said interbeat intervals to a computer.

25 19. The method of claim 18 wherein said personal physiological monitor includes a built in flash memory for storing physiological data and means for downloading said data to a computer at a later time.

30 20. The method of claim 15 wherein said sensor unit of said personal physiological monitor comprises a glove having embedded sensors that bring said sensors into contact with the skin of the user when worn in use, and further includes a flexible wristband having an LCD display operatively connected to said data processing unit.

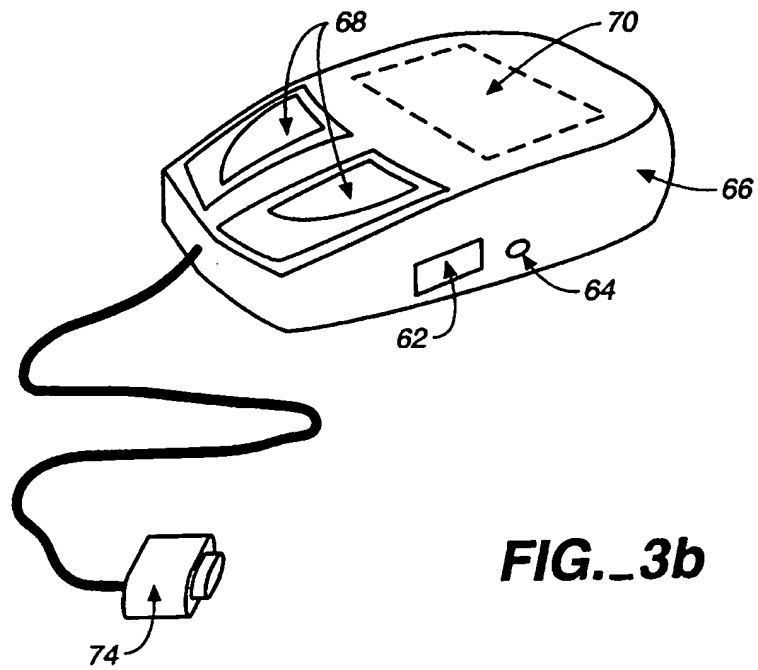
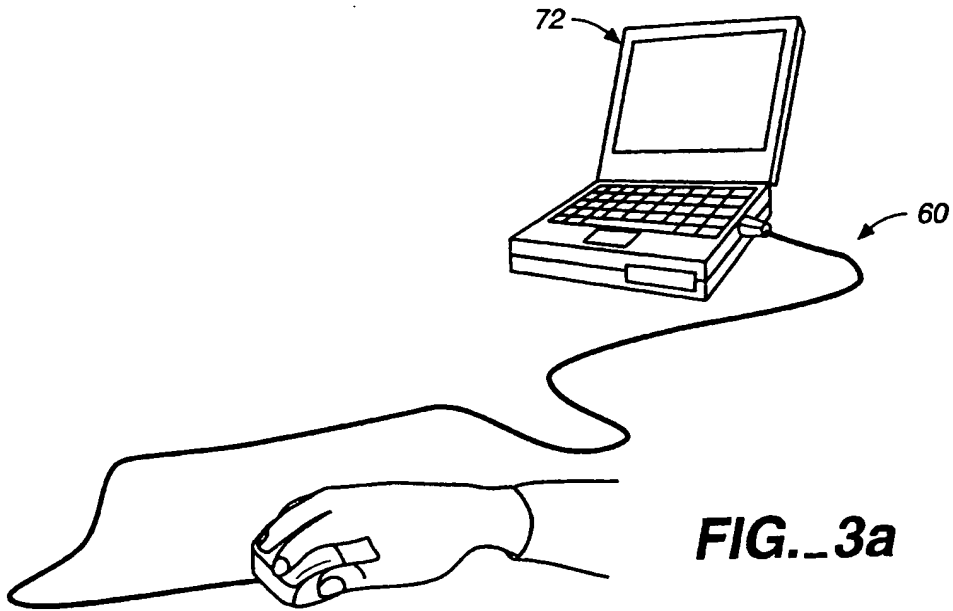
35

1 / 6

FIG._1a**FIG._1b****FIG._2a****FIG._2b**

SUBSTITUTE SHEET (RULE 26)

2 / 6



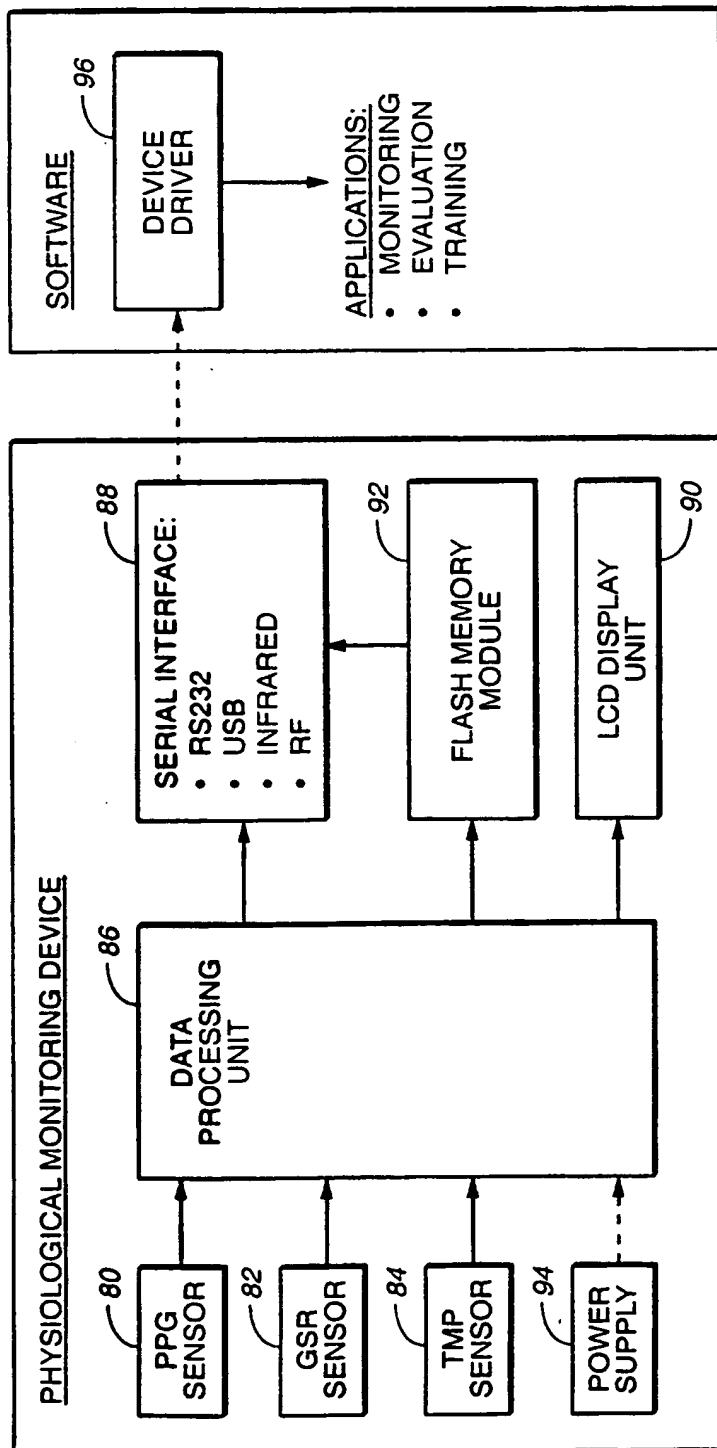
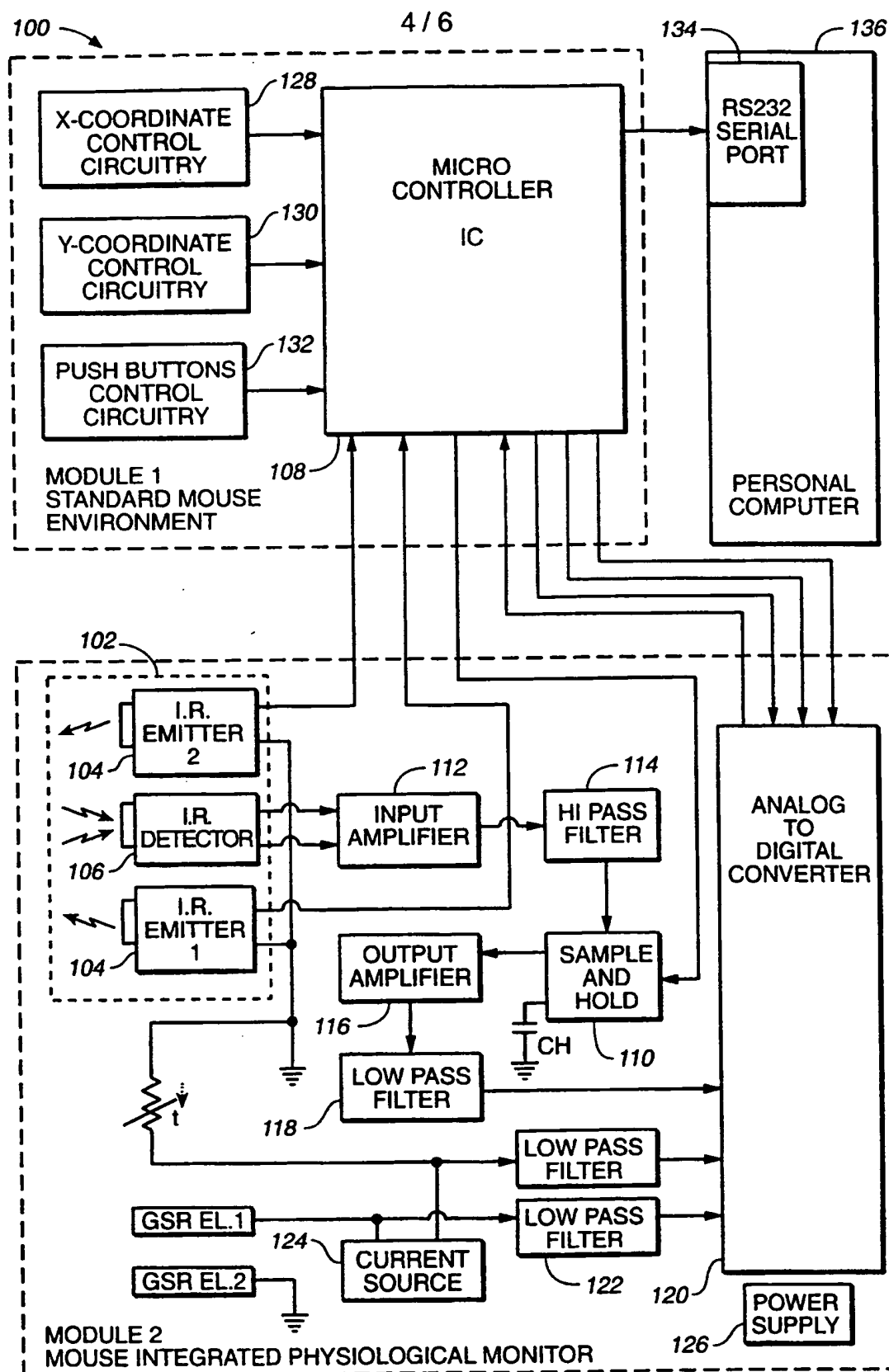


FIG. 4

**FIG. 5**

SUBSTITUTE SHEET (RULE 26)

